510(k) Summary of Safety and Effectiveness K05 3527

This 510(k) Summary of Safety and Effectiveness for the Spectra Hair Removal Laser is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and follows the HHS Publication FDA 95-4158 concerning the content and organization of a 510(k) summary.

Applicant:	SpectraGenics, Inc.
Address:	5880 W. Las Positas Blvd., Suite 52 Pleasanton, CA 94588-8552
Contact person:	Robert E. Grove, Ph.D.
Telephone:	(925) 701-2549
Preparation date:	December 3, 2007
Device Trade Name:	Spectra Hair Removal Laser System
Common Name:	Pulsed diode laser
Classification Name:	Laser Instrument, Surgical, Powered (Laser surgical instrument for use in general and plastic surgery and dermatology) Regulation No. 878.4810 Product Code: GEX; Panel: 79
Legally Marketed Predicate Devices:	Spectra Hair Removal Laser SpectraGenics, Inc. K032846, K052848 LightSheer (StarLight) pulsed diode laser Star Medical / Coherent Star K973324, K982940, K001746 SLP 1000 (LC 100) pulsed diode laser Palomar Medical Technologies, Inc. K013028, K010580, K011747 Apex 800 pulsed diode laser Iridex Corporation K020849

FEB - 1 2008

	F-1 pulsed diode laser Opusmed, Inc. K030235 SpaTouch® PhotoEpilation System Radiancy (Israel) Ltd. K020856 SpaTouch Pro PhotoEpilation System Radiancy (Israel) Ltd. Presumed to be K020856 SkinTouch Radiancy (Israel) Ltd. K030897, K051671 ABC Hair Removal System Palomar Medical Technologies, Inc. K060839
System Description:	The Spectra Hair Removal System consists of the Spectra Laser and Spectra Skin Sensor. The Spectra Hair Removal Laser is a semiconductor diode laser system that delivers infrared light at a wavelength of nominally 800 nm. The Spectra Skin Sensor determines whether users can safely use the Spectra Hair Removal Laser.
Intended Use of the Device:	The Spectra Hair Removal Laser System is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments.
Performance Data:	The specifications and indications for use of the Spectra Hair Removal Laser System are substantially equivalent to those claimed in the clearance for the above-listed predicate devices. Clinical data is provided to demonstrate the safety and efficacy of the Spectra Hair Removal Laser System in a simulated home-use environment to support the over-the-counter clearance.

Conclusion:	The Spectra Hair Removal Laser System is substantially equivalent to the legally-marketed claimed predicate devices for the purposes of this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2008

SpectraGenics, Inc.
% Robert E. Grove, Ph. D.
President & CEO
5880 West Las Positas Boulevard
Pleasanton, California 94588

Re: K053527
Trade/Device Name: Spectra Hair Removal Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 08, 2007
Received: August 13, 2007

Dear Dr. Grove:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053527

Device Name: Spectra Hair Removal Laser System

Indications For Use:

The Spectra Hair Removal Laser System is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053527